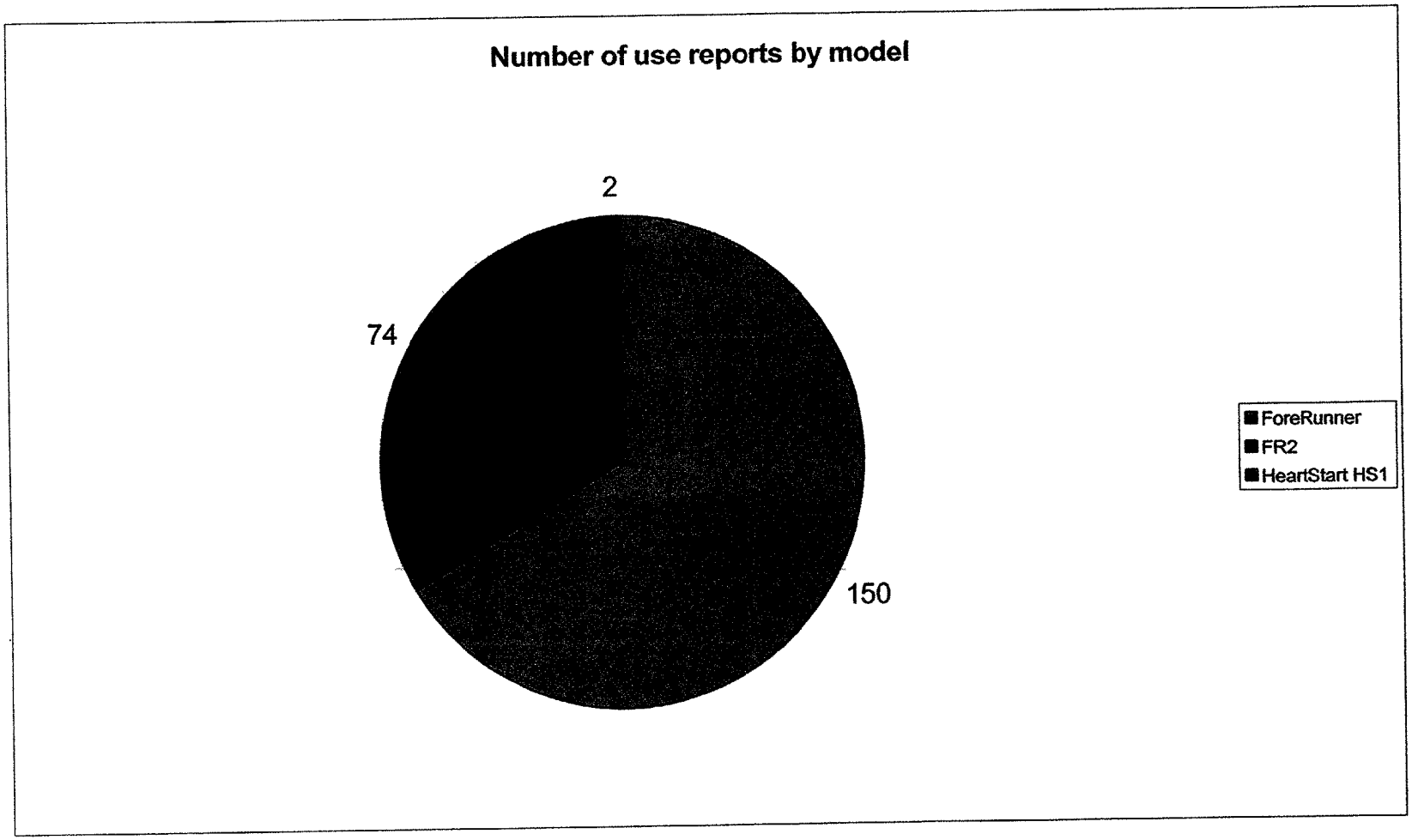
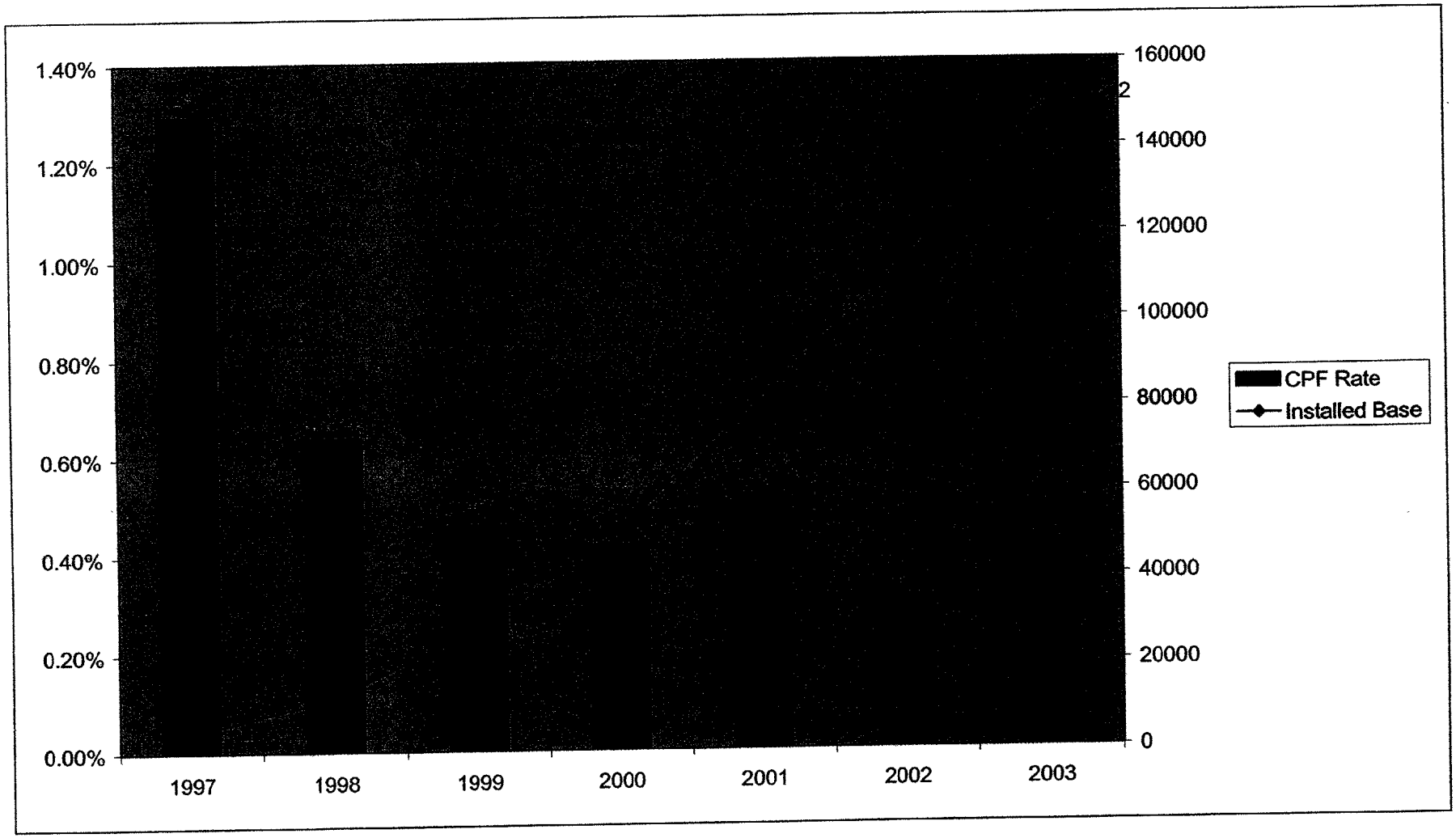

Number of use reports by model
2
74
150
ForeRunner
FR2
HeartStart HS1

Appendix C
Philips Installed Base for All AEDs and AED CPF Rates
January 1997 – December 2003


1.40%
1.20%
1.00%
0.80%
0.60%
0.40%
0.20%
0.00%
160000
140000
120000
100000
80000
60000
40000
20000
0
1997
1998
1999
2000
2001
2002
2003
CPF Rate
Installed Base

Attachment 1
Summary of MDR Reportable Events for All ForeRunner and FR2 Defi
December 1996 - December 2003

Group I – No Voice Prompts		
Event Description	**Investigation/Results/Conclusions**	**M**
Device passed BIT but the speaker produced no voice prompts. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
Unit used for demonstration displayed red X and produced no audio. No patient involvement.	Red X condition not confirmed, unit passed BIT. Speaker failure confirmed. The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
FR2 speaker not producing voice prompts, speaker appears to be defective. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
Unit's speaker output was intermittent and garbled. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
Device used for training stopped producing speaker output. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
Device passed BIT but the speaker produced no voice prompts. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
Speaker volume varied, from low to none. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
FR2 speaker not producing voice prompts. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
FR2 speaker not producing voice prompts. No patient involvement.	A review of the device record indicated that the customer installed an unrecognized battery into the device. During initial review, the speaker produced voice prompts. However, near the end of analysis, the device stopped producing voice output. The speaker coil measured open, and further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
FR2 speaker not producing voice prompts. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
Originally returned for service, no accompanying reason for return. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis determined that the speaker was weakened by operator error during manufacturing	303
Device produced no voice prompts. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303

Group I – No Voice Prompts		
Event Description	**Investigation/Results/Conclusions**	**N**
Device passed BIT but the speaker produced no voice prompts. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
Device passed BIT but the speaker produced no voice prompts. No patient involvement.	The ForeRunner produced no voice output because the point at which the speaker coil wire is tacked to the diaphragm was sheared off, resulting in collateral stress to the speaker coil through increased work hardening.	303
Device produced no voice prompts. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
Device speaker produced no voice prompts. No patient involvement.	Broken speaker wire at entry point to one of the two external solder joints.	303
Device passed BIT but the speaker produced no voice prompts. No patient involvement.	Product not returned. Therefore no investigation was possible.	303
Device passed BIT but the speaker produced no voice prompts. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
Device appears to work normally, but no output produced by the speaker. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
Voice prompts operated intermittently. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
Device stopped producing voice prompts during training. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
Device passed BIT but the speaker produced no voice prompts. No patient involvement.	Product not returned. Therefore no investigation was possible.	303
Device passed BIT but the speaker produced no output. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	303
Device stopped producing voice prompts during demonstration. No patient involvement.	Broken speaker wire at entry point to one of the two external solder joints. (Not inside the diaphram, unique at time of investigation)	303

Group I – No Voice Prompts			
Event Description	**Investigation/Results/Conclusions**	**MDR Number**	**Philips Reference Number**
Device stopped producing voice prompts during training. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	3030677-2001-00019	C01-001431
Device passed BIT but the speaker produced no output. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	3030677-2001-00014	C01-001384
Device passed BIT but the speaker produced no output. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	3030677-2001-00015	C01-001383
Device passed BIT but the speaker produced no output. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	3030677-2001-00016	C01-001382
Device passed BIT but no speaker output during user interactive portion of the test. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	3030677-2001-00017	C01-001335
User reported that the speaker was broken. Device still operational but emits no voice prompts. No patient involvement.	The device produced no voice output because the speaker coil measured open. Further analysis identified a broken wire in the coil winding caused by metal fatigue.	3030677-2001-00013	C01-001314
Device passed BIT but no speaker output during user interactive portion of the test. No patient involvement.	The device produced no voice output because a wire in the coil winding of the speaker was broken.	3030677-2001-00002	C01-001222
The unit did not pass emit voice prompts when the unit was turned on. No patient involvement.	A BIT was performed and passed except there were no voice prompts. Review of the device's internal records showed several low/dead battery messages. A second BIT was performed, without the pads attached, and the *apply pads* message was heard. The unit was disassembled and it was observed that there was an open circuit associated with the speaker.	3030677-2001-00011	C01-001025
No audio was generated from the speaker. Appropriate messages were displayed on the screen. No patient involvement.	Two speaker wires entering the speaker cavity were broken. Manufacturing process improvements made regarding wire stability. Updated users guide includes a clarification of instructions when audio cannot be heard.	3030677-2001-00009	C00-000929
Unit had no voice prompts and displayed a red X. No patient involvement.	It was observed on the returned unit that during power up, it would display a red x and chirp prior to initiating voice prompts. A weak solder joint was the cause. The vendor for this printed circuit board is no longer used.	3030677-2000-00007	C00-000889

Group I – No Voice Prompts			
Event Description	**Investigation/Results/Conclusions**	**MDR Number**	**Philips Reference Number**
Despite maximizing volume, no voice prompts. Messages on screen displayed appropriately. No patient involvement.	BIT successfully performed and passed on returned AED. When unit turned on, verified no volume. The unit was disassembled and it was observed there was a broken wire in the speaker.	3030677-2000-00006	C00-000884

Group II – Patient Connection			
Event Description	**Investigation/Results/Conclusions**	**MDR Number**	**Philips Reference Number**
User reported that poor contact between pads and patient prevented adequate contact for analysis and defibrillation of patient in cardiac arrest. The poor contact appeared to be the result of insufficient adherence of the center portion of each pad to the patient's skin.	Pads were received two months after the incident was reported and had been exposed during the intervening period. Inspection showed that the pad's gel was dry and not adhesive. The pads connector and wires were tested, finding that two shocks from a defibrillator could be successfully delivered with the pads. The pad's gel was inspected under magnification, revealing that numerous hairs and fibers of unknown origin and varying in length and color were present on the surface of the gel in different locations. First article samples retained by Heartstream and samples from the customer's inventory were tested; no anomalies were found. It is not possible to determine the impact of this issue on the patient's outcome.	3030677-2003-00048	C03-002375
User reported that the device did not recognize that defibrillation pads had been applied to a patient with severe psoriasis.	Adequate contact between pads and patient was not established at anytime during the incident. Impedance measurements exceeded the maximum specified impedance at which the device will begin analysis of 1500 ohms and typically exceeded 2000 ohms throughout the event. The device correctly functioned according to its design and specifications by instructing the responders with appropriate voice prompts to ensure that the pads were properly applied.	3030677-2003-00046	C03-002304
Unit advised and aborted three successive shocks. After the third shock abort, the unit turned itself off. The report indicated that the defibrillation pads may have been faulty or that the user did not follow each of the voice prompts produced by the unit.	Review of the ECG and device data showed that the FR2 performed according to its specifications. For each advised shock the impedance measured immediately prior to shock delivery was found to exceed the level specified for effective therapy and the safety of the patient and the AED operator. After each shock abort, the unit advised the user to address either the position of the pads, or to replace them in case of damage. After the third aborted shock, the FR2 is designed to shut down with a an error that can be cleared by the next complete BIT so that the user must address the issue. In this instance, the pads were then attached to another AED, and the issue persisted. The defibrillation pads used in the event were unavailable for the evaluation. It is not possible to determine the impact of this issue on the patient's outcome.	303677-2002-00029	C02-001668
Continuous voice prompt *to apply pads*. The first pad set was removed and a new set of pads used. Error message cleared by user.	The pads were discarded by the user, and not returned for evaluation. Review of the ECG data showed noise and appears to be due to intermittent pads connection. User followed instructions to replace pads and there was no patient impact.	3030677-2000-00005	C00-000737
Continuous *apply pads* message. A second defibrillator with new pads was used, 16 shocks given, patient subsequently expired later that day.	Different set of pads tried with the unit and worked ok. First pads then used with the same unit and apply pads message received. Electrical testing on the returned pads showed discontinuity in the pads that could have caused continued prompt.	3030677-1998-00010	C98-000342

Group II – Patient Connection			
Event Description	**Investigation/Results/Conclusions**	**MDR Number**	**Philips Reference Number**
After AED advised no shock, CPR initiated, unit then prompted to *apply pads* and displayed on the screen the device was inoperable and red x in the status screen. A second unit arrived, attached a new set of electrodes and patient pronounced at the scene.	The initial pads were not returned for analysis. A battery insertion self-test (BIT) was performed on the returned AED and successfully passed. The error code that generated the red x was recreated only by repeated connecting and disconnecting the battery in a simulated use condition, however, the unit started appropriately when the on button was pushed. It was concluded that there could have been an intermittent pads failure or poor pads contact between the pads and patient. The patient, however, was in asystole when the pads where applied, which is not a shockable rhythm. There was no patient impact.	242582-1998-000020	C98-000326
User reported that there was a possible issue with defibrillation pads or pad attachment to the patient.	The patient was dead for more than one hour, according to a physician on the aircraft. Review of the ECG data showed varying impedance, suggesting there may have been a pads issue, attachment of the pads to the patient issue or high impedance of the patient causing inaccurate ECG measurements. Since the pads and unit were not returned no further analysis possible. The user, however, had performed a BIT, the unit successfully passed and placed back into service. No patient impact.	3030677-1998-00007	C98-000293
Unit gave *attach pads* prompt although pads attached to the patient. The first pads were removed, a second set applied and unit functioned properly.	Examination of the first pad set showed small crack in the electrode conductive material that could have caused the continued prompt. Since a similar complaint was received from the same user, damage likely due to handling or storage.	3030677-1998-00006	C97-000187
Apply pads message received.	The actual pads were not returned but the device was returned. Unable to confirm event. ECG review indicated there may have been a problem with the pads or the pads connection to the patient. No patient impact.	3030677-1997-00005	C97-000156
Attach pads prompt received, reapplied pads and reinserted connector and the same prompt received. Same pads used with another unit and the same prompt received. New set of pads used, defibrillator advised shock, shock delivered, patient defibrillated.	Analysis of the pads showed a break in the in the tin material of the pads. The cause of the break that could have caused the continued prompt was not determined.	3030677-1997-00004	C97-000126

Group II – Patient Connection			
Event Description	**Investigation/Results/Conclusions**	**MDR Number**	**Philips Reference Number**
Attach pads prompt received, reapplied pads and reinserted connector and the same prompt received. Same pads used with another unit and the same prompt received. New set of pads used, defibrillator advised shock, shock delivered, patient defibrillated.	Analysis of the returned pads showed a break in the in the tin material of the pads. The cause of the break was not determined, but the break could have caused the continued prompts.	303677-1997-00003	C98-000085

Group III– Shock Decisions (Algorithm Sensitivity)			
Event Description	**Investigation/Results/Conclusions**	**MDR Number**	**Philips Reference Number**
User reported that the ForeRunner would not shock VF. The unit charged to shock but then aborted. The unit passed a BIT and indicated it was ready for use by displaying a black hourglass on in status indicator.	Passing a BIT indicates that the device is performing within its specifications. An evaluation of the event description by the Company concluded that the patient was most likely in low frequency VF, and below the ForeRunner's shock criteria. However, no ECG or other recorded event data was available for analysis.. The device indicated that no shock was advised and that an asystolic rhythm was displayed on the main screen of the device. Subsequent efforts by ALS personnel produced alleged VF. It is unknown if a shock may have benefited the patient.	3030677-2001-00025	C02-001509
Device initially advised shock but changed its decision.	Review of the ECG data by the Company showed the patient was fine VF and momentarily met the criteria for a shock advisory. However, due to changes in the rhythm before charging was complete, the unit disarmed and no further shockable rhythms were detected. The patient's rhythm (both frequency and amplitude) remained below the criteria for the device; the criteria were established to exclude low rate or artifact that are inappropriate to shock. Device performed within specifications. It is unknown if a shock may have benefited the patient.	303677-2001-00010	C01-001000
User questioned no shock advisory with patient in VF. CPR provided for nearly 10 minutes, shock advised and delivered and converted patient's VF to slow, organized rhythm. AED was then turned off and patient expired.	Review of the ECG data by the Company showed the patient was in very low frequency VF, typically associated with long down time. CFR improved patient's rhythm characteristics enough for shock advisory and shock delivery. Post shock the rhythm was converted to one with periods of asystole and brachycardia. When the AED was turned off, the heart rate was 17 beats per minute. The patient's rhythm was below the criteria for the device; the criteria were established to exclude low rate or artifact that are inappropriate to shock. Device performed within specifications. It is unknown if a shock may have benefited the patient.	3030677-2001-0008	C00-000968
No shock advised but paramedic on scene thought ECG display rhythm was shockable. Another defibrillator was deployed and shock delivered although patient was then pronounced.	Unit passed battery insertion test after the event. Physician review of the ECG stated it was not possible to determine if a shockable rhythm was present or not since there was significant artifact. The cause of the artifact was not determined. However the physician concluded that the rhythm was either asystole (not a shockable rhythm) or long downtime VF (which without CPR or drug administration unlikely to result productive rhythm.) Device performed within specifications. It is unknown if a shock may have benefited the patient.	24258852-2000-00052	C00-000708
Patient in fine VF, unit delivered three shocks then reversed two or three times shock advised decisions.	Review of the ECG data by the Company showed the patient was in very low frequency VF, typically associated with long down time (reported as 35 minutes). The patient's rhythm was below the criteria for the device; the shock decision criteria were established to exclude low rate or artifact that are inappropriate to shock. Manual shock capability possible but not used. Device performed within specifications. It is unknown if a shock may have benefited the patient.	3030677-1999-00002	C99-000593

Group III– Shock Decisions (Algorithm Sensitivity)			
Event Description	**Investigation/Results/Conclusions**	**MDR Number**	**Philips Reference Number**
Upon review of ECG, patient was in VF, unit advised a shock but no shock was delivered.	Review of the ECG data by the Company showed the patient was in very low frequency VF (occasionally the heart rate dropped below 135 beats per minute), typically associated with long down time. The patient's rhythm was below the criteria for the device; the criteria were established to exclude low rate or artifact that are inappropriate to shock. Device performed within specifications. It is unknown if a shock may have benefited the patient.	3030677-1999-00001	C99-000521

Group IV– Miscellaneous			
Event Description	**Investigation/Results/Conclusions**	**MDR Number**	**Philips Reference Number**
Customer reported that the device stopped working and displayed a red X on its status indicator during the incident after issuing voice prompts and prior to initiating patient analysis.	Evaluation of the cumulative device record and the annotated ECG file revealed that the battery was not latched properly into the battery compartment. The investigation found fault with neither the device nor the battery used during the incident. Patient impact is unknown.	3030677-2003-00047	C03-002393
User reported that the device indicated it was not ready for use (displayed a red X on its status indicator) when it was deployed during an event, and that the unit did not power on. The battery was replaced with a new battery and the unit continued to indicate that it was not ready for use. ECG from a second defibrillator showed that the presenting and prevailing rhythm was asystole; no shocks were delivered.	The unit was received for investigation with a battery installed, and it indicated it was ready for use (flashing hourglass on status indicator). A battery insertion test (BIT) was attempted but not completed. Analysis of the device identified a discrepant internal component. X-ray and analysis of the component by a third party investigator revealed that one of component's internal wires was displaced on the order of microns. Thermal expansion of the component's encapsulant material pushed the displaced wire into contact with the component's die and caused it to intermittently electrically short on an interval precisely daily such that the device would allow the daily self-test to pass and only display a solid red X for periods of hours a day.	3030677-2002-00040	C02-002000
After attaching a unit to the patient, the patient was moved, the unit dropped to the floor, a red x and device not ready message were displayed. Another crew arrived, attached a second defibrillator, no shock advised message and patient pronounced at scene.	Upon return, a BIT was performed and successfully passed. The unit passed several moreBITs and the unit evaluated using electrical and performance testing. None of these tests were able to recreate the events as described by the user. It is not possible to determine the impact of the unit's alleged behavior on the patient's outcome.	24582-1999-00015	C99-000478
Both defibrillation pads depicted the lower rib cage as the location to attach the pads. These pads were not used and another set was applied.	Confirmed observation and implemented corrective action with the pad manufacturer to reduce the chances of other occurrences. There was no patient impact.	242852-1998-00078	C98-000469

Group IV– Miscellaneous			
Event Description	**Investigation/Results/Conclusions**	**MDR Number**	**Philips Reference Number**
Unit did not display prompts at the beginning of an event, the unit was turned on/off button and unit worked fine. After event, status indicator intermittently indicated problem.	Analysis showed damage to the latch area of the battery caused incomplete insertion of the battery into the device. Cause of the damage is unknown, and it is not possible to determine the impact of this issue on the patient's outcome.	3030677-1998-00008	C98-000290
Zipper on unit carrying case broke after using the unit in a response. User unable to the close the carry case after the event. No patient involvement.	Carrying case was dirty and damaged and the zipper completely open. The AED, however, was not returned, indicating that the device could be accessed, if needed.	3030677-1997-00002	C97-000077
Difficulty unlocking the security bracket that holds the unit. No patient involvement.	The user identified worn keys causing intermittent difficulty with the bracket that holds the defibrillator in place on aircraft. The user believes copies are made of the same key, not replacing worn keys. No keys were returned for analysis.	3030677-1997-00001	C97-000072

Attachment 2
Summary of Device Failures for All ForeRunner, FR2, and HeartStart HS1 Defibrillators
December 1996 - December 2003

Defibrillator Model	Event Description	Investigation Results	Philips Number
ForeRunner*	"Not ready for use" prompt when powered on. Analysis of ForeRunner's internal memory revealed that the issue may have been discovered when the device was applied to a patient simulator. Follow-up with the user confirmed that the use was simulated.	Investigation traced root cause to a faulty component. The Paralyne coating on U2; chip placed on edge on PCB. The use was simulated. Therefore, there was no patient impact.	C01-001260
FR2	Unit was returned for routine service and was accompanied by a report that it did not successfully complete a BIT. No report of patient involvement was reported by the customer. Investigation of the ForeRunner revealed that unit was involved in an emergency use, during which an error was logged in the device's internal memory. The patient ECG file was subsequently requested by Philips and received.	Investigation determined that the unit issued an error warning at the end of a patient use after two shocks were delivered to the patient. The warning was issued because the high voltage capacitor fell out of tolerance for capacitance and dissipation.	C02-001897
FR2	Displayed solid red X during use	Investigation confirmed report, finding that a Female faston pushed off recipient male faston. The health care professional present during the incident concluded that the device's performance did not have an impact on the patient's outcome. Patient's pulse was restored to bradycardia changing to tachydardia by ALS personnel at the event.	C02-001976
FR2	Displayed solid red X during use	The unit was received for investigation with a battery installed, and it indicated it was ready for use (flashing hourglass on status indicator). A battery insertion test (BIT) was attempted but not completed. Analysis of the device identified a faulty internal component. X-ray and analysis of the component by a third party investigator revealed that one of component's internal wires was displaced on the order of microns. Thermal expansion of the component's encapsulant material pushed the displaced wire into contact with the component's die and caused it to intermittently electrically short. This in turn caused the unit's status to indicate a problem for only portions of each day until the part cooled enough to function normally and allow a daily self-test to pass. The patient was in seizure when the FR2 was applied, and it is unknown whether a shock would have benefited the patient.	C02-002000
FR2	Device delivered a shock, then the main screen became blank and shut itself off. The user turned the unit back on; unit analyzed, delivered second shock, reanalyzed and issued a no shock advisory	Investigation confirmed the users report, and traced the root cause to a faulty component. Self-test after use alerted user to request service. The responder present at the event stated that the performance of device did not affect outcome of the patient.	C03-002622
HS1	No Events Reported	N/A	N/A

***Occurred during simulated use testing, not reported as a failure by customer**

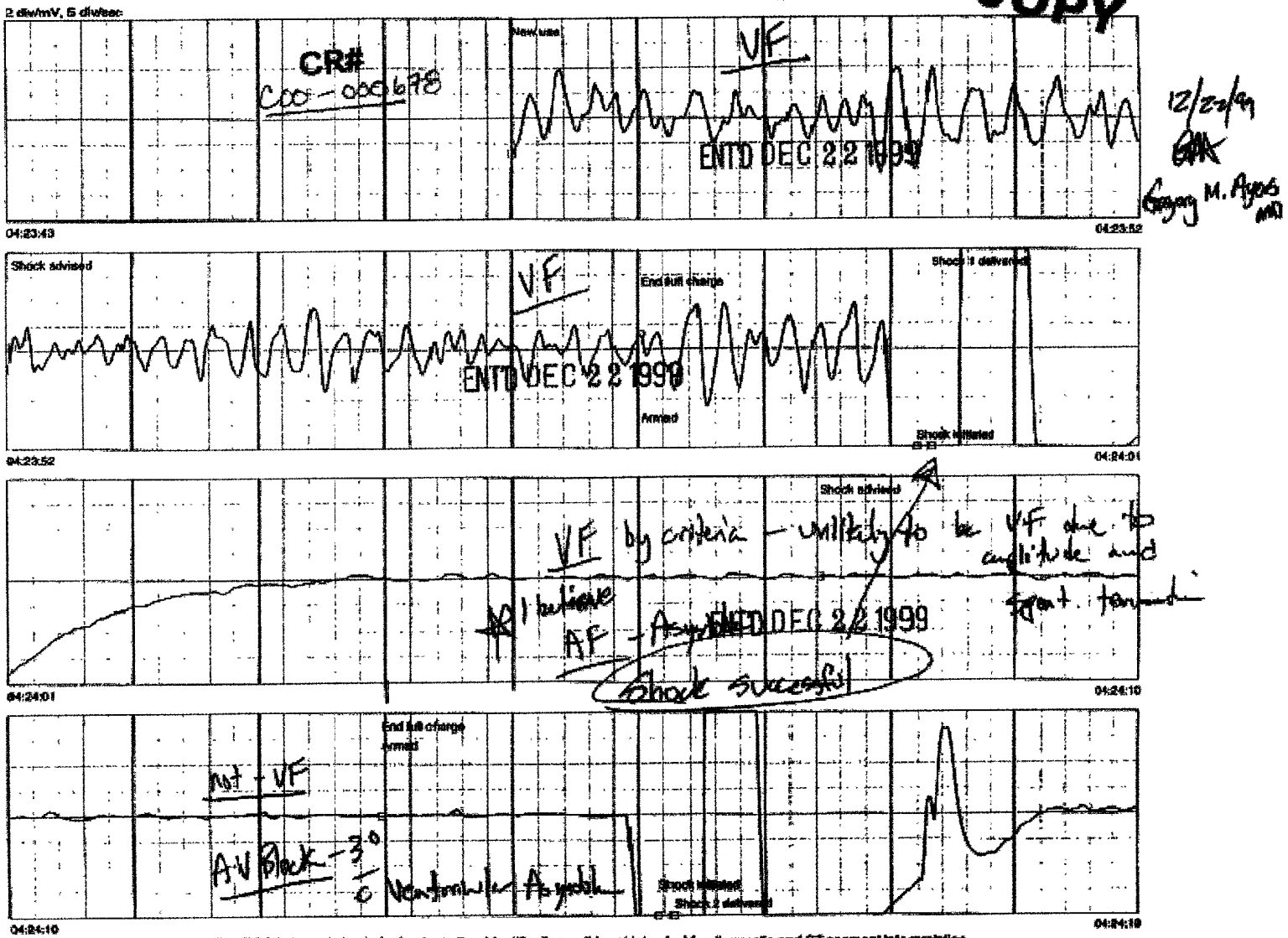
Attachment 3
ECG Record of Single Reported "Inappropriate Shock" and Independent Review by Final Overreading Physician

Incident Date: 11/22/99

ENTIRE ECG

Incident ID : Brug061

COPY



This ECG is intended only for basic rhythm identifications. It is not intended for diagnostic and ST segment interpretation.

Report creation date: 01/06/00 09:25:29 Page 1

Attachment 5

HEARTSTREAM **Controlled Document Release** DCRA: 3697

By: _____ Effective: _____

1. Purpose

The purpose of this procedure is to define field corrective actions (FCA) including product recalls, market withdrawals and product advisory letters, and to establish procedures and responsibilities for conducting, reporting and documenting these actions.

2. Scope

This procedure applies to Field Corrective Actions initiated by or on behalf of Heartstream affecting product distributed anywhere in the world.

3. Definitions - General

3.1. **Field Corrective Action:** Any action taken to modify the original characteristics, conditions of use, or availability of a distributed product. FCAs include product recalls, market withdrawals and corrections, and can also include advisory notices sent to field personnel, distributors and/or customers. Routine servicing and actions to improve product performance or quality which are not intended to reduce health risk or remedy a violation are excluded, as are stock recoveries and ship holds.

3.2. **Product Hold or Ship Hold:** A temporary disruption of normal movement of the product while an issue is investigated, risks analyzed and FCA strategy decisions are made. The disposition of a product hold may result in a FCA or release back to normal distribution.

4. Definitions – United States

4.1. **Product Recall:** The company's removal or correction of a marketed product that the Food and Drug Administration (FDA) would consider to be in violation of the laws it administers and against which the Agency would initiate legal action (i.e., seizure).

4.1.1. Recall does not include a market withdrawal or a stock recovery.

4.1.2. A product recall could include, not only products being physically removed from the marketplace, but also distribution of product information or advisory letters.

4.2. **Market Withdrawal:** The company's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation (i.e., normal stock rotation practices, routine equipment adjustments and repairs, etc.).

4.3. **Stock Recovery:** The company's removal or correction of a product that has not been marketed or that has not left the direct control of the company (i.e., the product is located on the premises owned by, or under the direct control of the company and which has not been released for sale or use).

4.4. **Correction:** Repair, modification, adjustment, relabeling, destruction or inspection of a product without its physical removal to some other location. Note: Routine servicing and upgrades of products which would not be considered to be violative are not included within the definitions of correction or removal.

4.5. **Product Advisory Letters:**

4.5.1. **Notification:** A communication issued by a manufacturer, distributor or other responsible person in order to notify health professionals and other appropriate persons of additional instructions or information regarding a product in commercial distribution and intended for human use.

4.5.2. **Safety Alert:** A communication issued voluntarily, or at the request of a regulatory agency, by a manufacturer, distributor or other responsible person to inform health professionals and other appropriate persons of a situation that may present an increased risk to health presented by a device in commercial distribution and intended for human use, in order to eliminate the risk.

4.6. **Recall Classification:** The designation (i.e., I, II or III) assigned in the United States by the FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled. (21 CFR 7.3(m)).

4.6.1. **Class I Recall:** A situation in which there is a reasonable probability that the use of, or exposure to, a violative product shall cause serious adverse health consequences or death.

4.6.2. **Class II Recall:** A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.

4.6.3. **Class III Recall:** A situation where the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

4.7. **Consignee:** Anyone who received, purchased or used the product being recalled.

5. Definitions - European Community

5.1. **Recall:** When there is a risk of death or serious deterioration to the state of health:

- the return of a medical device to the supplier;
- its modification by the supplier at the site of installation;
- its exchange; or
- its destruction;

in accordance with the instructions contained in an advisory notice.

5.2. **Advisory Notice:** A notice issued to provide information and/or advice on what action should be taken in the use, modification, disposal or return of a medical device.

6. Procedure

6.1. Responsibilities

6.1.1. The Heartstream Regulatory Affairs Manager is responsible for ensuring that FCA determinations are made in compliance with

this procedure. This includes chairing the necessary meetings to evaluate available information and determine whether a FCA is needed to reduce a risk to health or remedy a violation of a law or regulation that is applicable to a product that has been distributed to any country. In the event that the Regulatory Affairs Manager is not available at the time information about a problem suggests that a FCA may be warranted, the Heartstream Quality Assurance Manager is responsible for these activities.

6.1.2. Heartstream senior managers are responsible for evaluating available information and participating in the determinations of whether a FCA is needed to reduce a risk to health. Heartstream senior managers include the Quality Assurance Manager and Regulatory Affairs Manager in addition to all other senior managers who report directly to the Heartstream Operations Manager.

6.1.3. FCA proposals for other reasons (customer satisfaction, business reasons only) must be approved by the Operations Manager.

6.1.4. The Regulatory Affairs Manager is responsible for developing the plan for each FCA and assigning actions as needed to appropriate individuals to ensure completion of the FCA. In cases where the action is being taken for reasons other than to reduce a risk to health or remedy a violation, this responsibility may be delegated to another department (e.g., Marketing, Customer Service or Quality Assurance).

6.1.5. The Regulatory Affairs Manager is responsible for determining when reports of FCAs are required and for ensuring that the appropriated reports are filed with the authorities in accordance with the requirements outlined in this procedure.

6.2. Field Corrective Action Determination

6.2.1. The Regulatory Affairs Manager collects all available relevant data to aid in the determination of whether a field corrective action is required. This data includes, but is not necessarily limited to, information from the following sources:

- Risk analyses for the product developed per P03003, Hazard Analysis Process and/or P04012, Post-Market Risk Analysis Process
- Product specifications and instructions
- Applicable regulations and laws
- Previous FCA decisions made by Heartstream

6.2.2. If the information suggests that a FCA may be warranted, Regulatory Affairs calls a meeting of all available Heartstream senior managers to review the available information and make a FCA determination. If a meeting is not practical, then the Regulatory Affairs Manager may have separate discussions of the issue with the other available senior managers in series.

6.2.3. The dominant principle used in determining whether a field action is required is one of comparison of the relative risks. Decisions are made with an understanding that a program to remove or correct a number of distributed medical devices may present a greater risk to health than the problem itself.

6.2.4. If it is determined that a FCA is required, the Regulatory Affairs Manager notifies senior management and develops the FCA plan in conjunction with the FCA team (see the section below for FCA Plan Development).

6.2.5. If it is determined that a FCA is not required after information has been considered per this procedure, the following actions occur:

- Regulatory Affairs prepares a summary of the decision and supporting data. This document is contained or referenced in the CAPA item for the issue per P04011, Corrective and Preventive Action Process Flow.

- If any special monitoring of product performance is required, the person responsible for such monitoring and any related trending criteria and reporting requirements are identified within the decision summary described above.

6.3. FCA Plan Development

6.3.1. If it is determined that a FCA is required, then the Regulatory Affairs Manager has the responsibility of convening a FCA team of individuals as appropriate to develop the FCA plan and ensure the FCA is completed. The team typically includes representatives from Quality Assurance, Marketing, Customer Service, and Regulatory Affairs, with representatives from Information Systems, Engineering and Manufacturing as required based on the issue.

6.3.2. The FCA team determines the appropriate type of FCA to address (prevent and/or correct) the issue, and actions are assigned. The following factors are considered in development of each FCA plan:

- Results of the risk analysis and answers to applicable questions in Appendix I of P04012, Post-Market Risk Analysis process.
- The list of customers who received the product.
  - Consider using the product warranty, product registration and current customer databases from direct Philips purchases to generate customer information.
  - Consider relationships with distribution and marketing partners to communicate with customers and identify customer information.
- Consider using the exsiting customer tracking database.For those products not identified with a lot or serial number, determination of how identification in the field shall be made.
- Method for ensuring continued availability of essential product.
- Determination of the type and depth of the FCA or other action (i.e., recall, market withdrawal, correction, stock recovery, notification to customers or notification to field sales channels, etc.)
- Development of communications, both internal and external, regarding the FCA.
  - Consider public communication mechanisms, such as press releases, news media and the internet (i.e., Philips homepage, recall.gov).
- Determination of the disposition of returned products.

- Determination of the length of time to monitor returns.
- Establishment of an effectiveness check and the acceptable level of customer response.
- Estimation of the financial impact.
- Reconciliation of returned, destroyed or released product.
- Method and criteria for closing of the field corrective action.

6.4. Conducting the FCA

6.4.1. Regulatory Affairs is responsible for chairing the FCA team that conducts/coordinates FCAs. Regulatory Affairs is responsible for maintaining accurate records of the FCA progress and completion. Written notifications and contacts with customers/distributors, etc. are to be documented by the individual who notified or contacted the customers/distributors. All documentation relating to the FCA is forwarded to and maintained by Regulatory Affairs.

6.4.2. For guidance, the following levels of notification and effectiveness checks apply, based on US recall guidance. These guidelines may also be used to establish levels for equivalent recalls in other countries. Alternative decisions about notifications and effectiveness checks may be made on a case-by-case basis, with the rationale documented in the FCA plan.

United States Class I and II Recalls and Equivalent

- Written notification is made to the customer level.
- Territory sales personnel are notified.
- Means of notification is to be rapid and reliable (i.e., Federal Express or postal verification of receipt).
- Efforts to contact customers who do not respond to the first notification shall be made. This may involve phone calls, contacting the customer through sales channels, and/or other means to verify notification is received. Normally up to three attempts will be made to contact each customer before the recall is closed.

- In certain cases, the seriousness of the recall may require additional follow-up to ensure complete response.

United States Class III Recalls and Equivalent

- Notification may be made to the distributor and customer level.
- Territory sales personnel are notified.
- Means of notification is to be reliable (i.e., first class US mail).
- Customers who do not respond to the first notification shall normally be notified a second time before the recall is closed.

6.5. Regulatory Reportability

6.5.1. The Regulatory Affairs Manager or delegate determines the following:

- Whether a Report of Correction and Removal is required to be submitted to the FDA.
- Whether a notification to the European Competent Authorities, Notified Body and Authorized Representative is required.
- Whether the issue must be documented as a customer complaint per P01046, Complaint and Service Return Handling and Product Return System.
- Whether the issue needs to be filed as a Medical Device Report (MDR) per P04001, Medical Device Reporting or as a Vigilance report per P04003, Medical Devices Vigilance System Reporting.
- Whether any additional reports are required to regulatory agencies in other countries. Applicable corporate procedures are consulted as needed to assist in this determination.

6.5.2. For US Class I or II recalls and equivalent corrections or removals, the Regulatory Affairs Manager or delegate submits a written report of correction and removal to the local FDA district office within 10 working days after the removal or correction was initiated. The following information must be included in the report:

- Heartstream's establishment registration number, the date of the report, sequence number for the report and the report type designation of either "C" or "R" for correction or removal, respectively. These data should be indicated on one line, separated by dashes, (e.g., "3030677-1/1/99-001-C").
- The name, title, address and telephone number of the entity responsible for conducting the device correction or removal.
- The brand name and the common name, classification name or usual name of the device and the intended use of the device.
- Marketing status of the device, including any applicable 510(k) or other submission number.
- The model, catalog or code number for the device and the manufacturing lot or serial number of the device or other identification number.
- The manufacturer's name, address, telephone number and contact person if different from that of the person submitting the report.
- A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken.
- Any illness or injuries that have occurred with use of the device. If an MDR has been submitted in accordance with the Medical Device Reporting process P04001, reference to any related MDR numbers.
- The total number of devices manufactured or distributed subject to the correction or removal, and the number in the same batch, lot or equivalent unit of production subject to the correction or removal.
- The date of manufacture or distribution and the device's expiration date or expected life.
- The names, addresses and telephone numbers of all US and foreign consignees of the device and the dates and number of devices distributed to each consignee.
- A copy of all communications regarding the correction or removal and the names and addresses of any recipients of the communications which were not consignees of the device.

- If any of the required information listed in this section is not available, a statement as to why it is not available and when it is expected to be submitted.
- A disclaimer that the report does not constitute an admission that the device caused or contributed to a death or serious injury.

6.5.3. If it is determined that the same correction or removal previously reported to FDA will be extended to additional lots or batches of the same device, an amendment to the written report of the correction or removal shall be made to FDA within 10 working days of initiating the extension. The following information is required for a report amendment:

- Reference to the original correction or removal report number.
- The name, title, address and telephone number of the entity responsible for conducting the device correction or removal.
- Any information required for the original report which is different from the original report.

6.5.4. For all medical device removals or corrections which are not required to be reported to FDA, records will be maintained which include, at a minimum:

- The brand name and the common name, classification name or usual name of the device and the intended use of the device.
- The model, catalog or code number for the device and the manufacturing lot or serial number of the device or other identification number.
- A description of the event(s) giving rise to the FCA and the corrective or removal actions that have been, and are expected to be taken.
- Justification for not reporting the FCA to FDA, to be reviewed and approved by the Regulatory Affairs Manager or designee.
- A copy of all communications regarding the correction or removal.

6.5.5. For European recalls invovling medical devices, the Medical Device Directive requires any technical or medical reason for the systematic recall of a device to be reported by the manufacturer to the appropriate Competent Authorities.

- Removals from the market for purely commercial reasons do not require submission of a report.
- The manufacturer should send copies of recall reports to the Competent Authorities of the countries in which the recall is applicable, and to the Competent Authority of the member state in which the Notified Body is located, as applicable. This should be done before or at the same time that advisory notices are sent to the relevant users. Competent Authority addresses may be found in the Medical Devices Vigilance System Guidance.
- The authorized representative established in the European Community is to be informed of the recall and sent copies of advisory notices implementing recalls.
- The information is also submitted to the Notified Body.

6.5.6. For reportable European recalls, Regulatory Affairs Manager or delegate prepares and submits an initial report as required, including the following information:

- Details of the factors giving rise to the recall, including a summary of any relevant adverse incidents;
- Technical details of the device problem, if known;
- Potential hazard presented by use of the device;
- Circumstances under which the device is used and when the hazard may occur;
- Indication of likelihood of the hazard occurring;
- Conclusions of tests and other investigations on affected product or other samples if available;
- Recall letter (a draft letter is acceptable for initial reports);
- Whether the device is CE marked, and the device classification;
- Device model number/name and description;
- Lot or serial number(s) of affected devices;
- Dates when affected products were distributed;
- Customers of the affected product;
- Names of the EEA countries affected by the recall;
- The identity of the Notified Body where applicable.

6.5.7. For recalls of medical devices, the Regulatory Affairs Manager or delegate prepares and submits reports with appropriate authorities in other countries as required, in accordance with the relevant corporate procedures.

6.5.8. Interim status reports are filed as required by regulatory authorities within the timeframes they may specify for such reports.

6.6. Completion of a FCA

6.6.1. At the completion of a FCA, Regulatory Affairs is responsible for preparing a final summary report regarding the FCA. This report is signed by the Regulatory Affairs Manager and Quality Assurance Manager (at a minimum) and is maintained by Regulatory Affairs. The report includes the following information:

- the reason for the FCA.
- the effectiveness of the FCA.
- the disposition of returned products.
- references to the risk analysis and other corrective actions associated with the issue.
- inclusion or reference to all other documentation required to demonstrate that the approved FCA plan was fulfilled.

6.6.2. At the conclusion of a removal or correction that has been reported, the final report or notification letter is submitted to the regulatory authorities that received an initial report.

7. Revision History

Rev	DCRA #	Effective Date	Description of Change
A	0229	12/08/95	Initial Release
B	1269	08/03/98	Revise 3.1 and 3.5 to clarify definitions. Revise 5.1.1, 5.1.2, and 5.2.1 to clarify responsibility of RA and QA. Add 5.2.2 and renumber. Revise 5.2.2.3 to notify FDA if applicable. Add 5.2.3, 5.2.4 and 5.2.5. Revise 5.3.1 to clarify RA & QA responsibility.

C	2510	01/28/02	Retitle section 1 and renumber. Revise section 2 to clarify scope. Clarify sections 3.1 and 3.2. Remove section 3.3 and renumber. Remove section 3.6, move to general definitions. Remove section 3.7. Remove sections 3.10 and 3.11. Update section 4. Remove section 4.3. Clarify sections 4.5.1 and 4.5.2. Remove sections of procedure (section 5) and updated and added to the appropriate sections. Clarify sections 6.1.1 through 6.1.4. Added new 6.2.2 and renumbered. Updated 6.2.3. Clarified 6.2.4 and 6.2.5. Updated title of 6.3 and clarified 6.3.1, 6.3.2. Updated 7.2.4 and 7.2.5 and 7.3.1.
D	3697		Additional considerations for identifying customers and notification methods.